In the Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-605

UNITED STATES OF AMERICA, ET AL.,
Petitioners,

VERSUS

GLEN L. RUTHERFORD, ET AL.,
Respondents.

RESPONSE BRIEF TO PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

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January, 1979

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SCOPE OF BRIEF

This Brief is in response to the Petition for Writ of Certiorari to the United States Court of Appeals for the Tenth Circuit, filed by the Solicitor General on behalf of the United States.

ISSUES

The Petition for Certiorari lists the question presented for review as follows:

> "Whether the safety and effectiveness requirements of the Federal Food, Drug, and Cosmetic Act apply to drugs intended for use by the terminally ill."

Although it is difficult to clearly delineate the issues presented by the United States as reasons for granting the Petition to resolve the question presented, the following appear to be the issues:

1. The decision of the Court of Appeals is contrary to the meaning of the Food and Drug Act.
2. The Appeals Court decision limits the Commissioner's power to protect the public from unsafe and ineffective drugs.
3. The decision by the Appeals Court would prevent the Commissioner from concluding that any drug intended for use by the terminally ill has not been shown to be safe and effective.
4. The Appeals Court decision would make it difficult for the Commissioner to discharge his statutory responsibility to keep unproven drugs out of the marketplace.
5. As a separate basis, the United States argues that the Appeals Court decision is inconsistent with the decision in *Rutherford* v. *American Medical Ass'n*, 379 F.2d 641 (7th Cir. 1967, *cert. denied*, 389 U.S. 1043 (1968).

ARGUMENT AND AUTHORITIES

Initially, this Brief will deal with the purported inconsistency of Circuit Court opinions.

In the case *Rutherford* v. *American Medical Ass'n*, supra, an action was brought seeking an injunction against the Food and Drug Administration to order it to cease interfering with distribution of the drug Kreboizen.

The Court pointed out that there had been no attempted compliance with the Food, Drug and Cosmetic Act and therefore, that the Court did not have jurisdiction:

> "Without an attempted good faith application for approval or exemption, we have no jurisdiction to determine whether the FDA has illegally placed impossible or unreasonable conditions on approval or exemption, or has made requests for information impossible to fulfill, or whether the FDA has been dilatory, biased, or discriminatory."

In the instant case there has been a good faith application to the Food and Drug Administration. As pointed out in the Petition for Certiorari of the United States, this case was appealed to the Tenth Circuit Court of Appeals on one earlier occasion and at that time, the Tenth Circuit ruled that the preliminary injunction previously granted would remain in effect; however, the Court was of the opinion that there was probably no administrative record prepared by the FDA to support its conclusion that Laetrile was a "new drug." The Circuit Court of Appeals then ordered the District Court to remand the case to the FDA for proper administrative proceedings if the same were necessary.

In a later hearing before the Honorable Judge Luther Bohanon, the attorneys for the Food and Drug Administration stipulated that there was no administrative record and the case was subsequently remanded to the FDA. The Commissioner of the Food and Drug Administration published notice in the Federal Register of an administrative proceeding on Laetrile and also conducted two days of hearings in Kansas City.

After an immense record was amassed, the Commissioner issued his order finding that Laetrile was not exempt from the Act and that it should not be shipped in interstate commerce.

The Food and Drug Administration cannot complain that it was not given opportunity to conduct the initial administrative proceeding in regard to Laetrile. The United States District Court for the Western District of Oklahoma reviewed the entire administrative record and issued its order, setting that opinion aside. This decision has been affirmed by the Tenth Circuit Court of Appeals.

The entire basis for the Court's decision in *Rutherford* v. *American Medical Ass'n,* supra, was that the initial jurisdiction was in the FDA rather than the courts. In this case, the FDA has had opportunity to exercise initial jurisdiction and to make its administrative finding. That administrative finding is subject to judicial review: *Weinberger* v. *Henson, Westcott and Dunning,* 412 U.S. 609 (1973). In addition, the administrative decision to be affirmed must not be arbitrary, capricious or abusive of agency discretion; *Citizens to Preserve Overton Park* v. *Volpe,* 401 U.S. 402, 416 (1971).

The District Court for the Western District of Oklahoma, upon reviewing the administrative record, concluded:

> "Such decision is arbitrary, capricious, that it represents an abuse of discretion and is not in accordance with law. Consequently, it must be set aside and vacated."

The District Court did nothing it was not empowered to do and the Circuit Court of Appeals acted properly in affirming the District Court's decision.

Now we will turn our attention to the other arguments raised by the United States, those being primarily difficulties the agency will have if it is forced to abide by the Tenth Circuit ruling, and that the decision is contrary to the clear meaning of the Act.

A proper response to these arguments is best predicated upon a statement of the limitations imposed in the Tenth Circuit's Order. The Order of the Tenth Circuit contains the following explicit limitations:

1. The ruling applies only to "terminal" cancer patients.
2. The ruling applies only to Laetrile.
3. The ruling applies only to the liquid form of Laetrile.

Also to be considered is the fact that the FDA conducted an extensive administrative proceeding on the drug Laetrile before the District Court for the Western District of Oklahoma ruled upon the record and the Tenth Circuit Court of Appeals affirmed the District Court's decision.

Finally, consideration must be given to the fact that the term "life threatening" and "terminal" are not synonymous. There are many "life threatening" diseases for which there is an adequate remedy. There are no "terminal" diseases for which there is an adequate remedy; hence, the term "terminal."

The Government's Petition for Certiorari does not set out in detail the problems it anticipates in enforcing the Act if the decision of the Tenth Circuit stands. It merely says in conclusory terms that problems will exist.

It is difficult to fathom the problems the Commissioner will face when any other substance will have to withstand the same administrative and judicial review that Laetrile faced before any decision like this one could be rendered. The agency was not denied its right of administrative review and that administrative review is all that the Food, Drug and Cosmetic Act requires of the FDA.

The argument that the decision is contrary to the plain meaning of the Statute is spurious. Neither the Statute nor any cases cited thereunder have dealt with a specific class of "terminal" patients and the application of one specific substance (here Laetrile).

There is no question that the Food and Drug Administration is empowered to prevent unsafe and ineffective substances from reaching the general public; however, the extent of the FDA's power is not nearly so clearly established as the FDA asserts.

Both the District Court and the Tenth Circuit Court have faced the same problems in interpreting the duties of

the FDA in respect to "terminal" cancer patients. Both courts have had extreme difficulty in resolving the applicability of the terms "safe" and "effective" to an individual who has already heard the death knell from his doctor. For those patients there is certainly no orthodox "effective'" therapy or the patient would not be classified as "terminal."

The entire administrative record is bereft of any bona fide evidence that Laetrile is not "safe." Laetrile has been administered to tens of thousands of Americans, both in this country and in Mexico and there is not a single case of an individual being harmed by administration of Laetrile. The closest the FDA came to a safety issue was the assertion that certain individuals who had eaten apricot pits had suffered adverse reaction. Laetrile is not apricot pits but a derivative thereof. Additionally, there was no showing that the individuals who took the apricot pits were even cancer patients.

Neither the decision of the Circuit Court of Appeals nor the decision of the District Court for the Western District of Oklahoma impairs, in any way, the authority or prerogatives of the Food and Drug Administration. The Food and Drug Administration was given its opportunity to conduct its administrative proceeding. The fact that the administrative decision was overturned within the discretion of the reviewing court and the fact that the Food and Drug Administration has lost its case to this point does not mean that it has lost its administrative prerogatives. If the decisions of the Food and Drug Administration were not subject to being overturned, there would be no need for the judicial review provided.

CONCLUSIONS

For the reasons stated above, the Petition for the Writ of Certiorari by the United States Government should be denied.

Respectfully submitted,

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